Public Health

- **A CE is permitted to disclose PHI**
  - To a **public health authority** that is authorized by law to collect or receive the information for purposes
    - prevent or control disease
    - reporting of disease, injury, vital stats
    - public health surveillance, investigations or interventions, or
    - to a foreign agency cooperating with a public health authority
    - child abuse or neglect and to other authority authorized to receive such information

Public Health

- **A CE is permitted to disclose PHI**
  - **To an FDA official**
    - report adverse events relating to food or dietary suppl.
    - Product defects or problems
    - biological deviations
    - to track products
    - to enable product recalls, repairs & replacements
    - to conduct post marketing surveillance for FDA compliance

Public Health

- **A CE is permitted to disclose PHI**
  - **To a person** who may be at risk of contracting or spreading a communicable disease, provided the CE or PHA is authorized by law to make such contact
  - **To an employer** about a healthcare workforce member under certain restrictions
    - for purposes of recording work-related illness, injuries or workplace surveillance
    - if employer is required by law to record such information
    - if CE notifies the individual of the employer disclosure

Health Oversight Agency

- **A CE is permitted to disclose PHI**
  - **To a health oversight agency** for oversight activities authorized by law
    - audits; civil, administrative or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative or criminal proceedings or actions
    - for oversight of
      - healthcare system
      - gov't benefit programs making beneficiary eligibility determinations
      - determining compliance to government programs
      - determining compliance to civil rights laws

Research

- **A CE is permitted to disclose PHI**
  - For research
    - regardless of the source of funding
    - if Board approval of a waiver of individual authorization
    - by either an IRB or Privacy Board
  - For review prior to research
    - Sole purpose
    - PHI is necessary
    - No PHI is removed from the CE premises
  - For research using decedent information
    - Sole purpose
    - PHI is necessary
    - Verification of death

Research

- **Privacy Board Members**
  - Privacy rights competency
  - Unaffiliated with the CE, the research entity or sponsor
  - No conflict of interest
- **Waiver Documentation**
  - Name of IRB or Board and approval date
  - Statement of Satisfaction of Waiver Criteria
  - Description of PHI required
  - Whether normal or expedited review procedures were used

Research

- **Statement of Satisfaction of Waiver Criteria**
  - PHI involves minimal risk to individuals
  - No adverse effect on individual privacy rights or welfare
  - Research is not practical without the waiver and PHI
  - Trade off between individual privacy risks and research benefits is reasonable
  - Adequate plan to protect & destroy identifiers
  - Adequate assurance against re-use or disclosure
  - Signed by Chair or designee

Research

- **IRB**
  - Must follow the Common Rule and normal review procedures -- CFR
- **Privacy Board**
  - Normal Review
    - must review at a regular meeting with a quorum with at least one Unaffiliated member present
  - Expedited Review
    - may be used when research involves only minimal privacy risk to individuals
    - review must be performed by Board Chair or designees

Privacy Board

- **Comments**
  - Privacy Board is a function of the CE
    - may be shared function only if Affiliated Entity
  - Privacy Board does not replace the need for an IRB
    - IRB still required to satisfy physical or mental harm to participants and researchers
    - Privacy Board would co-exist with IRB
  - IRB can incorporate a Privacy Board
    - operate as a committee of the IRB with decision making authority for privacy waivers
  - Expedited Review
    - recommend a well defined policy for determining minimal privacy risk